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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,164	11/26/2003	Stephan R. Targan	066783-0142	8299

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,164	TARGAN ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 2-4, 9-10, 16-18 and 19-21, drawn to a method of diagnosing or predicting susceptibility to a clinical subtype of Chron's disease in a subject having Chron's disease comprising determining the presence of or absence of IgA anti-I2 antibodies and a NOD2 variant; classified in Class 435, subclass 7.1.

II. Claims 2, 5, 11-12, 16-18, 19 and 22, drawn to a method of diagnosing or predicting susceptibility to a clinical subtype of Chron's disease in a subject having Chron's disease comprising determining the presence of or absence of IgA anti-I2 antibodies and anti-Saccharomyces cerevisae antibodies (ASCA); classified in Class 435, subclass 7.1.

III. Claims 2, 6 and 16-19, drawn to a method of diagnosing or predicting susceptibility to a clinical subtype of Chron's disease in a subject having Chron's disease comprising determining the presence of or absence of IgA anti-I2 antibodies and anti-OmpC antibodies; classified in Class 435, subclass 7.1.

IV. Claims 2, 7,13-14, 16-18 and 23, drawn to a method of diagnosing or predicting susceptibility to a clinical subtype of Chron's disease in a subject having Chron's disease comprising determining the presence of or absence of IgA anti-I2 antibodies, NOD2 variant and anti-Saccharomyces cerevisae antibodies (ASCA); classified in Class 435, subclass 7.1.

V. Claims 16-18 and 19, drawn to a method of diagnosing or predicting susceptibility to a clinical subtype of Chron's disease in a subject having Chron's

disease comprising determining the presence of or absence of IgA anti-I2 antibodies and perinuclear anti-neutrophil cytoplasmic antibodies (pANCA); classified in Class 435, subclass 7.1.

VI. Claim 27, drawn to a method of determining a risk of having or developing a clinical subtype of Chron's disease, said clinical subtype characterized by fibrostenosis or the need for small bowel surgery comprising determining the presence or magnitude of IgA anti-I2 antibody response in a subject; classified in Class 435, subclass 7.1.

VII. Claim 28, drawn to a method of determining a risk of having or developing a clinical subtype of Chron's disease characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery in a subject having Chron's disease comprising determining the presence or magnitude of IgA anti-OmpC antibody response in the subject; classified in Class 435, subclass 7.1.

VIII. Claims 25-26 and 29, drawn to a method of determining a risk of having or developing a clinical subtype of Chron's disease characterized by fibrostenosis, internal perforating disease or the need for small bowel surgery in a subject having Chron's disease, comprising determining the presence, absence or magnitude of IgA anti-I2 antibodies, anti-Saccharomyces cerevisiae antibodies and IgA anti-OmpC antibodies; classified in Class 435, subclass 7.1.

Claims 1, 8,15 and 24 link inventions I-V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 1, 8, 15 and 24. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking

claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. Groups I-VIII are different methods. The methods of diagnosing or predicting susceptibility to clinical subtype of Chron's disease in a subject having Chron's disease using IgA anti-I2 antibodies and a NOD2 variant (Group I), IgA anti-I2 antibodies and anti-Saccharomyces cerevisae antibodies (Group II), IgA anti-I2 antibodies and anti-OmpC antibodies (Group III), IgA anti-I2 antibodies, NOD2 variant and anti-Saccharomyces cerevisae antibodies (Group IV) or IgA anti-I2 antibodies and perinuclear anti-neutrophil cytoplasmic antibodies (Group V) differ from the methods of determining a risk of having or developing a clinical subtype of Chron's disease of Groups VI-VIII using presence or magnitude of IgA anti-I2 antibody response (Group VI), the presence or magnitude of IgA anti-OmpC antibody response (Group VII) or presence, absence or magnitude of IgA anti-I2 antibodies, anti-Saccharomyces cerevisiae antibodies and IgA anti-OmpC antibodies (Group VIII) with respect to pathology, ingredients, method steps and endpoints. Therefore, each method is patentably distinct.

3. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct

method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

4. Irrespective of whichever group applicant may elect, applicant is further required under 35 U.S.C 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If any of Groups I or IV is elected, applicant is required to elect a single NOD2 variant selected from R702W, G908R and 1007fs. The NOD2 variants differ with respect to their structures, modes of action and physiochemical properties. Therefore, each represents a patentably distinct species.

B. If any of Groups I-V is elected, applicant is required to elect a single clinical subtype of Chron's disease as recited in claims 16-18. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

5. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina

Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 19, 2006
Nora M. Rooney, M.S., J.D.
Patent Examiner
Technology Center 1600

Maher M. Haddad

MAHER M. HADDAD
PATENT EXAMINER